

## REMARKS

Claims 1, 6-9-21, and 26-27, and 29-30 are pending in the present Application. Claim 26 has been amended, canceled or added, leaving Claims 1, 6-9-21, and 26-27, and 29-30 for consideration upon entry of the present amendment. Reconsideration and allowance of the claims are respectfully requested in view of the above amendments and the following remarks.

### Claim Rejections Under 35 U.S.C. § 103(a)

Claims 1, 6, 10 - 14 and 16 - 21 stand rejected under 35 U.S.C. § 103(a), as allegedly unpatentable over U.S. Patent Application No. 2002/0177899 to Eum et al. (hereinafter “Eum”), in view of U.S. Patent No. 6,153,252 to Hossainy et al. (hereinafter “Hossainy “). (Office Action dated 11- 17 – 2008, page 2) Applicants respectfully traverse this rejection.

Claim 1 is directed to a medical device comprising: a nickel-titanium based shape memory alloy having a reverse martensitic transformation start ( $A_s$ ) temperature of about 10°C to about 15°C and a transformation finish temperature ( $A_f$ ) of about 30°C to about 35°C; and a drug coating comprising a polymeric resin and one or more biologically active agents.

For an obviousness rejection to be proper, the Examiner must meet the burden of establishing that all elements of the invention are disclosed in the prior art; that the prior art relied upon, or knowledge generally available in the art at the time of the invention, must provide some suggestion or incentive that would have motivated the skilled artisan to modify a reference or combined references. *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). “A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *KSR Int’l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007). To find obviousness, the Examiner must “identify a reason that would have prompted a person of ordinary skill in the art in the relevant field to combine the elements in the way the claimed new invention does.” *Id.*

Eum teaches a method of preparing Nitinol devices for insertion into the body. (see Col. 1, lines 1 – 3) Eum teaches that the stent is cooled to a temperature below the martensitic finish temperature ( $T_{mf}$ ) prior to insertion into the delivery catheter. (see paragraph [0007]) Eum teaches that the stent is preferably manufactured from Nitinol and is fabricated with an Austenite start temperature ( $T_{as}$ ) of 0 to 20°C, preferably in the range of 10°C or higher and an Austenite finish temperature ( $T_{af}$ ) of 25 to 45°C, preferably 30 ± 5°C. (see paragraph [0010]) In contrast,

the Applicants claim is directed to a reverse martensitic transformation start (A<sub>s</sub>) temperature of about 10°C to about 15°C. The reverse martensitic transformation start (A<sub>s</sub>) temperature is not the same temperature as the Austenite start temperature (T<sub>as</sub>) and is generally lower than the Austenite start temperature (T<sub>as</sub>).

Eum refers to the reverse martensitic transformation start temperature in paragraph [0011] using the notation T<sub>ms</sub>, and states that it is lower than the temperature at which martensite to austenite conversion (see the location of T<sub>as</sub> in the Fig. 2) occurs on heating. The difference between the reverse martensitic transformation start (A<sub>s</sub>) temperature and Austenite start temperature (T<sub>as</sub>) can be seen in the Fig. 2 of Eum. In the Fig. 2, the reverse martensitic transformation start temperature (denoted as A<sub>s</sub> by the Applicants and as T<sub>ms</sub> by Eum) can be seen to be lower than the austenite start temperature (T<sub>as</sub>).

Thus the range proposed by Eum for its austenite start temperature is the range where the Applicants have claimed their reverse martensitic transformation start (A<sub>s</sub>) temperature. Eum therefore does not teach all elements of the claimed invention.

Hossainy is directed to a process for coating stents comprising contacting the stent with a liquid coating solution containing a film forming biocompatible polymer under conditions suitable to allow the film forming biocompatible polymer to coat at least one surface of the stent. (Abstract) In discussing the film-forming polymers that may be used for coating, Hossainy discloses that “the polymers molecular weight [is] high enough to provide sufficient toughness so that the polymers will not be rubbed off during handling or deployment of the stent and must not crack during expansion of the stent.” (Col. 5, lines. 43-47) Subsequently, the reference goes on to disclose the optimal melting point of the polymer, and that elastomers are the preferred types of polymers. Specifically, Hossainy discloses that “[e]lastomers present the advantage that they tend to adhere well to the metal stents and can withstand significant deformation without cracking”. (Col. 7, lines 5-57)

While Hossainy discloses film-forming polymeric coatings, the reference too does not disclose all elements of present Claim 1. Specifically, Hossainy does not disclose or suggest a nickel-titanium based shape memory alloy having a reverse martensitic transformation start temperature (A<sub>s</sub>) of about 10°C to about 15°C and a transformation finish temperature (A<sub>f</sub>) of about 30°C to about 35°C. For at least this reason, the combination of Eum and Hossainy does not teach or suggest every element of the present claims. Further, since Hossainy does not make

up for the deficiency of Eum, Applicants contend there would be no motivation to combine the references.

In addition, the Applicants contend that Eum teaches away from the claimed invention. Since Eum teaches that the reverse martensitic transformation start temperature is lower than its austenite start temperature, and its austenite start temperature was from 0 to 20°C, the reverse martensitic transformation start temperature prescribed by Eum would have to be less than the presently claimed value of 10 to 15°C.

Eum actually prescribes a range for its reverse martensitic transformation temperature that is in the vicinity of -10°C. Eum teaches that a freeze spray is used to cool the stent to -10°C, eliminating the potential for creating stress induced martensite, and providing a lengthy period for manipulation. (see paragraph [0010]) Eum also states that the loading of the stent occurs when the stent consists entirely of Nitinol in its thermally induced martensite form. (see paragraph [0010]) Clearly, for the stent to be in its martensitic state for an extended period of time (after being cooled to -10°C) would require the reverse martensitic transformation temperature to be in the vicinity of -10°C, which is far lower than the claimed value of 10 to 15°C. Case law holds that “[O]bviousness can be rebutted by showing that “the prior art teaches away from the claimed invention.” *In re Geisler*, 116 F.3d 1465, 1471 (Fed. Cir. 1997).

In summary, the Applicants believe that neither Eum nor Hossainy teach all elements of the claimed invention. In addition, Eum in teaching a reverse martensitic transformation temperature that is in the vicinity of -10°C, which is far lower than the claimed value of 10 to 15°C, teaches away from the claimed invention. For at least these reasons, the Applicants believe that the Examiner has not made a *prima facie* case of obviousness over Eum in view of Hossainy. The Applicants respectfully request a withdrawal of the obviousness rejection and an allowance of the claims.

Claims 7 and 9 stand rejected under 35 U.S.C. § 103(a), as allegedly being unpatentable over Eum and Hossainy as applied to Claim 1 above and further in view of U.S. Patent No. 4,770,725 to Simpson et al. (hereinafter “Simpson”) (Office Action dated 11-17-2008, page 5) Applicants respectfully traverse this rejection.

Claims 7 and 9 depend from Claim 1. Applicants respectfully submit that the combination proposed by the Examiner does not teach a nickel-base shape memory alloy having

a reverse martensitic transformation start temperature of about 10°C to about 15°C as required by Claim 1.

As noted above, neither Eum nor Hossainy teach a nickel-base shape memory alloy having a reverse martensitic transformation start temperature of about 10°C to about 15°C. Eum, in fact teaches a reverse martensitic transformation start temperature that is in the vicinity of –10°C.

Simpson is directed to nickel-titanium-niobium alloys that have 2.5 to 30 wt% niobium and show a widening of the transformation hysteresis. (see Description of the Invention) The compositions disclosed by Simpson do not have a reverse martensitic transformation start temperature of about 10°C to about 15°C. (see Tables 5, 6 and 9) For this reason at least, Simpson does not make up for the deficiency of Eum or Hossainy, and the combination of Eum and Hossainy in view of Simpson does not teach all elements of Claim 1. The Applicants respectfully request a withdrawal of the obviousness rejection and an allowance of the claims.

Claim 8 stands rejected under 35 U.S.C. § 103(a), as allegedly being unpatentable over Eum and Hossainy as applied to Claim 1 above and further in view of U.S. Patent No. 6,911,041 to Zscheeg. (hereinafter “Zscheeg”) (Office Action dated 11-17-2008, page 5) Applicants respectfully traverse this rejection.

Claim 8 depends from Claim 1. As noted above, neither Eum nor Hossainy teach a nickel-base shape memory alloy having a reverse martensitic transformation start temperature of about 10°C to about 15°C. Eum, in fact teaches a reverse martensitic transformation start temperature that is in the vicinity of –10°C.

Zscheeg teaches an expandable stent for insertion into the body lumen. (see Abstract) Zscheeg teaches that the stent comprises 54.5 to 57 wt% nickel and 43 to 45.5 wt% titanium. (see Col. 7, lines 48 – 52) Zscheeg however does not teach that the nickel titanium alloy has a reverse martensitic transformation start temperature of about 10°C to about 15°C as presently claimed. For this reason at least, Zscheeg does not teach all elements of the claimed invention. The combination of Eum with Hossainy and further in view of Zscheeg therefore does not teach all elements of the claimed combination. The Applicants respectfully request a withdrawal of the obviousness rejection and an allowance of the claims.

Claims 1 and 15 stand rejected under 35 U.S.C. § 103(a), as allegedly being unpatentable over Eum in view of U.S. Patent No. 6,517,858 to Le Moel et al. (hereinafter “LeMoel”). (Office Action dated 11-17-2008, page 6) Applicants respectfully traverse this rejection.

As discussed previously, Eum does not disclose all elements of present Claim 1. Specifically, Eum does not disclose or suggest a nickel-based shape memory alloy having a reverse martensitic transformation start temperature of about 10°C to about 15°C.

LeMoel is directed to a bioactive implant comprising a substrate coated with a polymer layer with reactive functions, and a bioactive substance fixed on the implant by means of said reactive functions. (Abstract) The reference discloses the fixation of a heparin compound onto the polymer layer during the radiografting of the polymer precursor by adding the heparin to the grafting medium containing the precursor monomer to be grafted. (Col. 5, lines 52-57) LeMoel discloses that the substrate of the implant may be a metal or a metallic alloy. (Col. 2, lines 33-36) However, LeMoel does not disclose all elements of Claim 1.

While LeMoel discloses a metallic implant coated with a polymeric resin and a biological agent, LeMoel does not disclose or suggest that the medical device is a nickel-based shape memory alloy having a reverse martensitic transformation start temperature, and a transformation finish temperature of about 30 to about 35°C, as provided by present Claim 1. For at least this reason, the combination of Eum and LeMoel does not teach or suggest every element of the present claims. Further, since LeMoel does not make up for the deficiency of Eum, Applicants contend there would be no motivation to combine the references.

Applicants therefore believe that the Examiner has not made a *prima facie* case of obviousness over Eum in view of LeMoel. Applicants respectfully request a withdrawal for the obviousness rejection and an allowance of the claims.

Claim 26 stands rejected under 35 U.S.C. § 103(a), as allegedly being unpatentable over Eum in view of U.S. Patent No. 6,911,041 to Zscheeg. (hereinafter “Zscheeg”) (Office Action dated 11-17-2008, page 7) Applicants respectfully traverse this rejection.

Claim 26 depends from Claim 22. Claim 22 is directed to a nickel-titanium alloy composition comprising about 55.5 weight percent of nickel based on the total composition of

the alloy; wherein the alloy has a reverse martensitic transformation start ( $A_s$ ) temperature of about 10°C to about 15°C. It is to be noted that Claim 22 is currently withdrawn from consideration.

As noted above, neither Eum nor Zscheeg teach an alloy having a reverse martensitic transformation start ( $A_s$ ) temperature of about 10°C to about 15°C. For this reason at least, neither Eum nor Zscheeg teach all elements of the claimed invention. Since neither Eum nor Zscheeg teach all elements of the claimed invention there is no motivation to combine them. Applicants therefore believe that the Examiner has not made a *prima facie* case of obviousness over Eum in view of Zscheeg. Applicants respectfully request a withdrawal for the obviousness rejection and an allowance of the claims.

Claim 27 stands rejected under 35 U.S.C. § 103(a), as allegedly being unpatentable over Eum and Zscheeg as applied to Claim 26 above, and further in view of Hossainy (Office Action dated 11-17-2008, page 7) Applicants respectfully traverse this rejection.

Claim 27 depends from Claim 26, which depends from Claim 22. As noted above, Claim 22 requires a nickel-titanium alloy composition comprising about 55.5 weight percent of nickel based on the total composition of the alloy; wherein the alloy has a reverse martensitic transformation start ( $A_s$ ) temperature of about 10°C to about 15°C.

It is to be noted that Claim 22 is currently withdrawn from consideration. In addition, Hossainy also does not disclose or suggest a nickel-titanium alloy composition comprising about 55.5 weight percent of nickel based on the total composition of the alloy, wherein the alloy has a reverse martensitic transformation start ( $A_s$ ) temperature of about 10°C to about 15°C, and thus does not disclose a stent manufactured from such an alloy. For at least these reasons Hossainy does not disclose or suggest every element of the present claims. Further, since Hossainy does not make up for the deficiencies of Eum or Zscheeg, there would be no motivation to combine the references. Applicants therefore believe that the Examiner has not made a *prima facie* case of obviousness over Cox in view of Hossainy. Applicants respectfully request a withdrawal of the obviousness rejection and an allowance of the claims.

Claim 29 stands rejected under 35 U.S.C. § 103(a), as allegedly being unpatentable over Eum in view of Simpson (Office Action dated 11-17-2008, page 8) Applicants respectfully

traverse this rejection.

Claim 29 depends from Claim 28, which has been withdrawn. Claim 28 as presently amended is directed to a nickel-titanium-niobium alloy composition comprising about 48 weight percent nickel and about 14 weight percent niobium, based on the total composition of the alloy, with the remainder of the alloy being titanium; wherein the alloy has a reverse martensitic transformation start ( $A_s$ ) temperature of about 10°C to about 15°C.

As noted above, Eum does not teach an alloy having a reverse martensitic transformation start ( $A_s$ ) temperature of about 10°C to about 15°C. Eum instead teaches a Nitinol that is fabricated with an austenite start temperature ( $T_{as}$ ) of 0 to 20°C, preferably in the range of 10°C or higher and an austenite finish temperature ( $T_{af}$ ) of 25 to 45°C, preferably  $30 \pm 5^\circ\text{C}$ . (see paragraph [0010]) Eum therefore does not teach all elements of the claimed invention.

Simpson teaches a nickel-titanium niobium alloy. (see Abstract) Simpson, like Eum, does not teach an alloy having a reverse martensitic transformation start ( $A_s$ ) temperature of about 10°C to about 15°C. (see Tables 5, 6 and 9 of Simpson) Thus, both Eum and Simpson do not teach all elements of the claimed invention. In addition, since Eum and Simpson do not teach all elements of the claimed invention, there is no motivation to combine references. Applicants therefore believe that the Examiner has not made a *prima facie* case of obviousness over Eum in view of Simpson. Applicants respectfully request a withdrawal of the obviousness rejection and an allowance of the claims.

Claim 30 stands rejected under 35 U.S.C. § 103(a), as allegedly being unpatentable over Eum in view of Simpson and further in view of Hossainy (Office Action dated 11-17-2008, page 8) Applicants respectfully traverse this rejection.

Claim 30 depends indirectly from Claim 28. As noted above, neither Eum, Simpson nor Hossainy teach an alloy having a reverse martensitic transformation start ( $A_s$ ) temperature of about 10°C to about 15°C. For this reason at least, the combination does not render the claimed invention obvious. In addition, since neither Eum, Simpson nor Hossainy teach all elements of the claimed invention, there is no motivation to combine references.

Applicants therefore believe that the Examiner has not made a *prima facie* case of obviousness over Eum in view of Simpson and further in view of Hossainy. Applicants respectfully request a withdrawal of the obviousness rejection and an allowance of the claims.

It is believed that the foregoing amendments and remarks fully comply with the Office Action and that the claims herein should now be allowable to Applicants. Accordingly, reconsideration and withdrawal of the objection(s) and rejection(s) and allowance of the case are respectfully requested.

If there are any additional charges with respect to this Amendment or otherwise, please charge them to Deposit Account No. 06-1130.

Respectfully submitted,

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